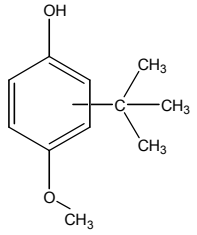
BUTYLATED HYDROXYANISOLE (BHA)
CAS No. 25013-16-5
First Listed in the *Sixth Annual Report on Carcinogens*



CARCINOGENICITY

Butylated hydroxyanisole (BHA) is *reasonably anticipated to be a human carcinogen* based on sufficient evidence of carcinogenicity in experimental animals (IARC V.40, 1986; IARC S.7, 1987). When administered in the diet, butylated hydroxyanisole induced papillomas and squamous cell carcinomas of the forestomach in rats of both sexes and male Syrian Golden hamsters. There is no evidence that butylated hydroxyanisole is carcinogenic to mice when administered topically or by subcutaneous or intraperitoneal injection. In a study which was reported to the IARC Working Group as an abstract and which became available subsequent to the meeting of the Working Group, administration of butylated hydroxyanisole in the diet induced papillomas and carcinomas of the forestomach in mice. (IARC V.40, 1986; Masui et al., 1986).

There are no data available to evaluate the carcinogenicity of butylated hydroxyanisole in humans (IARC V.40, 1986; IARC S.7 1987).

PROPERTIES

BHA, a white or slightly yellow waxy solid, is a mixture of 3-*tert*-butyl-4-hydroxyanisole and 2-*tert*-butyl-4-hydroxyanisole. It melts at 45-63 °C and has a boiling point of 264-270 °C. BHA is flammable, with a flash point of 156 °C. BHA has a faint characteristic odor. It is insoluble in water; it is freely soluble in 50% ethanol, other alcohols, propylene glycol, petroleum ether, and fats and oils. Commercial food-grade BHA is generally a mixture with >85% 3-*tert*-butyl-4-hydroxyanisole (3-BHA) and <15% 2-*tert*-butyl isomer (2-BHA) (Lam et al., 1979; IARC V.40, 1981). Food-grade BHA is >98% pure (NRC, 1972). BHA exhibits antioxidant properties as a scavenger of free radicals. It degrades after prolonged exposure to sunlight. When heated to decomposition, BHA emits acrid and irritating fumes.

USE

The primary use for BHA is as an antioxidant and preservative in food, food packaging, animal feed, and cosmetics, and rubber and petroleum products as well. Antioxidants are used to delay the deterioration of food flavors and odors and substantially increase the shelf life of many foods (Kirk-Othmer V.3, 1978). Since 1947, it has been added to edible fats and fat-containing foods for its antioxidant properties; it prevents food from becoming rancid and developing objectionable odors (Lam et al., 1979; IARC V.40, 1986). Antioxidants in cooking oils are used primarily for their carry-through and stabilizing effects on fried products; these effects are

essential to the success of several commercial fried foods (Kirk-Othmer V.3, 1978). BHA is added to butter, lard, meats, cereals, baked goods, sweets, beer, vegetable oils, potato chips, snack foods, nuts and nut products, dehydrated potatoes, and flavoring agents. It is used in sausage, poultry and meat products, dry mixes for beverages and desserts, glazed fruits, chewing gum, active dry yeast, defoaming agents for beet sugar and yeast, and emulsion stabilizers for shortenings (Kirk-Othmer V.9, 1978 and V.16, 1981; IARC V.40, 1986). BHA is widely used in the food industry. It is used in foods cooked or fried in animal oils because of its high thermal stability and its ability to remain active in baked and fried foods (LeFaux, 1968; Kirk-Othmer V.13, 1981). Its antioxidant properties are not lost during cooking; BHA-stabilized ingredients may be used to produce stabilized products (Kirk-Othmer V.9, 1978). BHA stabilizes the petroleum wax coatings of food packaging (Sax and Lewis, 1987). BHA is considered a GRAS (generally recognized as safe) compound by the FDA when the content of the antioxidant is not greater than 0.02% w/w of the total fat or oil content of the food.

Antioxidants retard the oxidation of vitamins A and E, carotene, xanthophyll pigments, rendered fats, and vegetable oils in animal feeds; BHA is one of the primary antioxidants used in these feeds (Kirk-Othmer V.3, 1978). It is an effective stabilizer for essential oils, paraffin, and polyethylenes (LeFaux, 1968).

BHA is used as a preservative and antioxidant in pharmaceutical preparations and cosmetic formulations containing fats and oils (Osol, 1980). Cosmetic-grade BHA reportedly contains a minimum of 90% 3-BHA and approximately 8% 2-BHA (IARC V.40, 1986). In a 1981 FDA survey, BHA was reported to be used in 3,217 to 21,279 cosmetic formulations; the majority (88%) of the reported concentrations was $\leq$ 0.1% (IARC V.40, 1986). One product, a lipstick, was reported to contain > 10% BHA. In this survey, lipstick formulations (1,256 products) represented the highest use of BHA, with eye shadows being the next highest (410 products). A widely used antioxidant mixture for cosmetics contained 20% BHA, 6% propyl gallate, 4% citric acid, and 70% propylene glycol (Kirk-Othmer V.7, 1979; IARC V.40, 1986).

PRODUCTION

The 1997 *Directory of Chemical Producers* lists two producers of BHA; no volumes, however, were disclosed (SRIa, 1997). In its latest and final editions, USITC (1993-1995) did not list BHA, but for 1990 and 1991 two manufacturers of the chemical were identified (USTIC, 1991, 1993). In 1982, the same number of major BHA producers were found in the United States (Giragosian, 1982; IARC V.40, 1986). Suppliers of the chemical, however, are abundant. The 1998 *Chemical Buyers Directory* lists 11 such companies, while *Chemcyclopedia 98* lists three (Tilton, 1997; Rodnan, 1997).

EXPOSURE

Potential for consumer exposure to BHA by ingestion and dermal contact is widespread. In 1975 the estimated average daily intake of BHA in the diet was 4.3 mg (IARC V.40, 1986). It is a widely used food additive in products containing vegetable oils or animal fats. It retains its antioxidant properties even at high temperatures. The general population may be exposed to BHA in butter, lard, meats, cereals, baked goods, sweets, beer, vegetable oils, potato chips, snack foods, nuts, dehydrated potatoes, flavoring agents, sausage, poultry and meat products, dry mixes for beverages and desserts, glazed fruits, chewing gum, active dry yeast, defoaming agents for beet sugar and yeast, and emulsion stabilizers for shortenings. The estimated U.S. consumption of BHA in food increased to 660,000 lb/yr during 1970-1982, up from 374 lb/yr in

1960 (Anonymous, 1983; IARC V.40, 1986). Reported annual consumption for BHA in the mid-1970s was 990,000 lb compared with 3.1 million lb for butylated hydroxytoluene (BHT) (Kirk-Othmer V.3, 1978). Industrial use of BHA has largely been replaced by *tert*-butylhydroquinone (TBHQ) (Kirk-Othmer V.11, 1980).

Potential dermal exposure exists for the population that uses cosmetics, especially lipstick and eye shadow. BHA is also used as an antioxidant for some rubber and petroleum products, and it is a stabilizer for vitamin A.

Potential occupational exposure exists for workers in certain industries, including food producers, animal feed producers, livestock producers, cosmetic manufacturers, some petroleum workers, and rubber producers and those who handle the end products such as tires. Fast food service personnel who normally cook and serve fried and oily foods have the potential for high exposure to BHA. BHA is volatile at 150-170 °C and is readily lost from thermal processes generating steam (Kirk-Othmer V.11, 1980). The National Occupational Exposure Survey (1981-1983) estimates that 32,553 total workers, including 7,933 women, are potentially exposed to BHA (NIOSH, 1984).

REGULATIONS

EPA regulates butylated hydroxyanisole under the Food, Drug, and Cosmetic Act (FD&CA). FDA also regulates use of BHA under FD&CA as a direct or indirect food ingredient. OSHA regulates BHA under the Hazard Communication Standard and as a chemical hazard in laboratories. Regulations are summarized in Volume II, Table B-16.